

Non-Technical Abstract

This protocol has been designed to investigate gene transfer of Vascular Endothelial Growth Factor DNA (phVEGF₁₆₅), which may repair a damaged blood vessel wall to help the process of opening blockages with a balloon catheter (percutaneous transluminal coronary angioplasty or PTCA). The protocol has the following two objectives.

Objective #1: is to determine the safety of coronary gene transfer of phVEGF₁₆₅ to increase the rate of repair of the artery wall following PTCA in patients with blocked coronary arteries.

Objective #2: is to obtain preliminary data regarding activity of gene transfer in the artery wall with phVEGF₁₆₅ for prevention of the recurrence of blockages in the blood vessel.

The protocol has been designed as a Phase I single-site, dose-escalating study of phVEGF₁₆₅ gene transfer directly into the blood vessel wall, in patients undergoing coronary artery PTCA and insertion of a single 13-28 mm metal stent inside the artery to hold the artery open. Patient Eligibility includes Males or Females ≥ 21 years with evidence of coronary artery disease in a vessel ≥ 2 mm indicated for treatment by PTCA and insertion of a single 13-28mm metal stent. Up to 12 patients will be enrolled and treated for this study over a period of 1 year.